

REMARKS

This Letter and Response to Final Rejection is respectfully submitted in order to transmit the attached Request for Continued Prosecution, Petition for Extension of Time, Petition to Change Inventorship, the accompanying Assignment and Supplemental Declaration and an Information Disclosure Statement, Form PTO-1449 and accompanying references.

Applicants respectfully amend the Specification of the above-captioned patent application in order to correct the claim of benefit of priority to Provisional Patent Application No. 60/069,797 filed December 16, 1997. This claim of priority was inadvertently omitted in the original Declaration and was only discovered upon recent review of the application file. Applicants also respectfully submit herewith a Supplemental Declaration which both reflects the proper inventorship and amends the Declaration to reflect the relationship between the above-identified patent application and Provisional Patent Application No. 60/069,797, filed December 16, 1997, which was inadvertently omitted from the original declaration. Applicants respectfully request that the claim of the benefit of priority from Provisional Patent Application No. 60/069,797 be granted.

Applicants also respectfully submit that the inventorship of the above-identified patent application inadvertently omitted Dr. Michael Costanzo when the application was originally filed. The remaining inventors are in agreement with adding Dr. Costanzo to the inventorship, as evidenced by the attached Petition to Change Inventorship and Supplemental Declaration.

The Final Rejection of October 25, 2004 rejected claims 24 and 28-35 under 35 U.S.C. 102(b) as being anticipated by Limtrakul et al. Claims 24, 28-36, 38, 40, 44-47 and 58 were further rejected under 35 U.S.C. 102(b) as being anticipated by Kosaka and JP 62036304 (Katsumi).

Applicants respectfully request reconsideration of the above-mentioned rejections under 35 U.S.C. 102 and 103(a) in light of the foregoing amendments to the claims and the ensuing discussion.

The Final Rejection rendered October 25, 2004 objects to applicants' distinction between the claimed method set forth in claims 24, 28-36, 28, 40, 44-47 and 58 and Limkatrul

et al., Kosaka and Katsumi. As has been noted on several occasions during the course of the prosecution of the above-captioned patent application, soy products containing soy trypsin inhibitor activity were well-known to be dangerous for human ingestion. [See Declaration of Katharine Martin filed March 7, 2002] Soy products containing such activity can cause, for example, gastric distress [Martin Declaration, ¶4], morphological alterations of small intestinal epithelium in calves [Martin Declaration, ¶5] and pancreatic enlargement [Martin Declaration, ¶5].

Thus, whether or not Limkatrul et al., Kosaka or Katsumi indicated that the soybean milk protein administered to the mice in Limkatrul's study contained soy trypsin inhibitory activity, those of ordinary skill in the art would not have expected to be able to administer soybean milk protein containing soy trypsin inhibitory activity to a human being.

Furthermore, Kosaka neither suggests nor describes the claimed method of using soy products. Kosaka merely refers to the use of papain, an enzyme found in papaya, in combination with citric acid, for therapeutic effects on diseases of the circulatory and digestive systems. Kosaka does not teach or suggest topical formulations or applications nor does it recognize the use of soy products for phagocytosis. The Final Rejection states, with respect to Kosaka, that "...it is known that tofu contains soybeans. Tofu is eaten by humans as a food source. Thus, if tofu can be eaten by a human so can soybean milk." [Final Rejection, p.3] While applicants recognize that tofu is eaten as a food source, tofu is another soy product that is **processed and cooked prior to eating** such that the soy trypsin inhibitory activity is removed from the food. Soybean milk that is intended for human consumption is also processed to remove the dangerous STI activity prior to ingestion. These soy products are distinguishable from the compositions and methods of applicants' invention which **do** contain soy trypsin inhibitory activity. Thus, Kosaka neither suggests nor describes the methods of applicants' invention.

While Katsumi refers to the use of soybean milk as a "cosmetic" or as a preventative for chapped skin or itching, nowhere does it suggest or describe the use of non-denatured soy products containing soy trypsin inhibitory activity for increasing or decreasing phagocytosis.

Applicants therefore respectfully request reconsideration of the rejections of claims 24, 28-36, 38, 40, 44-47 and 58 under 35 U.S.C. 102 as being anticipated by Limkatrul et al., Kosaka and Katsumi and under 35 U.S.C 103 in view of Limkatrul taken with Kosaka or Katsumi.

The Final Rejection further rejected claims 24, 28-36, 38, 40, 44-47 and 58 provisionally under 35 U.S.C. 102(e) as being anticipated by copending patent application Serial No. 09/110,409 and under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-60 of U.S. Patent Application Serial No. 9/110/409. Should claims become granted in the copending patent application, applicants will address the foregoing provisional rejections.

Applicants respectfully request correction of the claim of the benefit of priority with respect to the abovementioned provisional patent application, addition of Michael Costanzo to the inventorship of the above-captioned patent application and reconsideration of the rejections set forth in the Final Rejection of October 25, 2004. An early allowance is earnestly solicited.

Respectfully submitted,

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